UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,979	04/09/2007	Stanley M. Lemon	265.00410101	9290

26813 7590 09/14/2009

MUETING, RAASCH & GEBHARDT, P.A.
P.O. BOX 581336
MINNEAPOLIS, MN 55458-1336

EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
09/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,979	LEMON ET AL.	
	Examiner	Art Unit	
	BAO LI	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,14-36 and 41-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,14-36 and 41-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summery

1. The amendment filed on June 17, 2009 has been noted Claims 1, 14, 18, 26 and 33 have been amended. Claims 9-13, 37-40, 44-46 have been canceled. Claims 1-8, 14-36, 41-43 are pending. Claims 1-8, 14-36 and 41-43 with species of an arginine mutation at amino acid position 2040 are examiner.

2. Because no argument has been filed in regarding the restriction/election requirement. The restriction/election is then made Final.

Sequence requirements

Applicants' sequence listing submitted on April 8, 2009 has been accepted.

Specification

3. (Withdrawn) The objection of specification has been removed in view of Applicants' amendment.

Claim Rejections - 35 USC § 101

4. (Withdrawn) The rejection of claims 1-2, 4-8 and 41 under 35 U.S.C. 101 has been removed necessitated by Applicants' amendment.

5.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. (Maintained) Claims 1-8, 14-35 and 41-43 are still rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Applicants submit that independent claims 1, 14, 18, 26 and 33 have been amended to cite the percentage identity of the amino acid sequence encoded by the claimed polynucleotide having at least 90% to the amino acid sequence of SEQ ID NO: 2, therefore, the rejection should be removed.

9. Applicants' argument and amendment have been respectfully considered; however, it is not found persuasive, because the amended claims still fail to specify the reference sequence

from where the amino acid positions cited in claims are numerated. As indicated in the previous office action that HCV varies in length. Genotype 1a and 1c have a polyprotein of 3022 aa, 1b isolates are 3010 aa, HCV-N isolate has 3014 aa, and 2a and 2b isolates are 3033 aa, 2c isolate is 3037 aa, JK049 isolate is 3022 aa and JK046 is 3016 aa substantiated by the disclosure of Chamberlian et al. (J. Gene. Virol. 1997, Vol. 78, pp. 1341-1347). Please specify the reference sequence from where the ordinary number of amino acid residues is counted.

10. New Ground of Rejection:

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1-8, 14-36 and 41-43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for having an isolated replication competent polynucleotide encoding a HCV polyprotein with particular adaptive substitution mutations at amino acid residue S2204I in combinations with K1694R, F2080V and Q1609R or S2204I in combinations with K1694R and Q1609R together in SEQ ID NO: 2, wherein such mutations make the HCV replicon as replication competent, does not reasonably provide enablement for having a polynucleotide encoding any HCV genome being replication competent as long as the HCV polynucleotide sequence with at least 90% identity to a amino acid sequence set forth in SEQ ID NO: 2 and having a substitution mutations at amino acid residue S2204I in combination with any one amino acid mutation cited above. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

13. The test of scope of the enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the application coupled with information known in the art without undue experimentation (See United States v. Theketronic Inc., 8USPQ2d 1217 (fed Cir. 1988). Whether undue experimentation is required is not based upon a single factor but

rather a conclusion reached by weighting many factors. Theses factors were outlined in Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in re Wands, 8USPQ2d 1400 (Fed. Cir. 1988) that include 1). The nature of invention; 2). The scope of claims, 3). State of art; 4). Unpredictability of the field; 5). Working example presented by the Application; 6). A guidance provided by the Application, 7). Level of skill in the art and time for fulfill the scope of claims encompassed. These factors are all analyzed and discussed set forth below:

14. The nature of the clamed invention is directed to an isolated replication competent polynucleotide encoding a HCV polyprotein with particular adaptive substitution mutations at amino acid residue S2204I in combination with K1694R in NS4A, F2080V in NS5A and/or Q1609R at NS3 region, wherein the mutations make the HCV replicon as replication competent genome. However, the broadly reasonable interpretation of the claimed scope encompasses any HCV genome being replication competent as long as the HCV polynucleotide sequence has at least 90% identity to a amino acid sequence set forth in SEQ ID NO: 2 and comprises a substitution mutations at amino acid residue S2204I in combination with only one of the mutation cited above.

15. The state of art teaches that subgenomic HCV can be used for making a replicon to express HCV polyprotein in full or in part. However, the random mutation(s) made intentionally or unintionally, it is very unpredictable for the replication ability of the resulting HCV replicon in host cells as experienced and evidenced by artisans in the field. For example, Applicants themselves also (please see Yi et al. J. Virol. 2004, Vol. 78, No. 15, pp. 7904-7915) demonstrates that the combination of the consensus mutation S2204I in combination with mutation F2080V or K1691R or Q1067R alone does not replicate in host cell. Even the consensus mutation S2204I in combinations with Q1067R and F2080V makes the resulting HCV replicon not replication competent (See Fig. 4, especially the Fig. 4C).

16. Moreover, the scope of claims is also directed to a genome that Applicants do not describe which 10% genome can be mutated and how to mutate each of these 10% genetic codes, such that the HCV replicon can be replication competent.

17. Therefore, specification does not provide sufficient evidence and guidance for the broad scope of the claims encompassed.

18. The level of making a particular amino acid mutation adapted for a HCV becoming a replication competent polynucleotide is considerable high and unpredictable in the art above master degree of science level.

19. Given the above analysis of the factors which the courts have determined are critical in asserting whether a claimed invention is enabled, it must be considered that the skilled artisan would have to conduct undue and excessive experimentation in order to practice the claimed invention.

20.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BAO LI whose telephone number is (571)272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nickol Gary can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao Qun Li/
Examiner, Art Unit 1648